



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/303,315	04/30/1999	EUGENE S. PEARLMAN	108604/002	8170
7590 07/02/2004 Rashida A. Karmali, PhD 99 Wall Street 13th floor New York, NY 10005			EXAMINER CLOW, LORI A	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 07/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

3041-
Office Action Summary

Application No.

09/303,315

Applicant(s)

PEARLMAN, EUGENE S.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-17, 19-21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 13-17, 19, 20 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 21, 23, 24, 26, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5 April 2004 has been entered.

For purposes of clarity it is noted that the following claims are currently pending: 1-11, 13-17, 19-21, and 23-27. It is also noted that claims 1-4, 21, 23, 24, 25, and 27, drawn to hepatitis are considered elected. Claims 5-11, 13-17, 19, 20, and 25 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species. Election was made **without** traverse in Paper No. 7 and acknowledged by the Examiner in the Office Action dated 13 March 2001.

Claims 12, 18, and 22 have been cancelled.

The rejection under 35 USC 102(e) of claims 1-4 and 21-24 is hereby withdrawn in view of Applicant's response.

Applicant is reminded to follow the proper procedures set forth in the Federal Register, June 30, 2003 (Vol. 68, No. 125) outlining proper amendment format.

Claim Objections

Claim 1, step (a) recites "and tests ordered sent". This is improper grammar and should be amended to recite "tests ordered". Appropriate correction is requested.

Art Unit: 1631

Claim 1, step (f) recites “clinical test of each”. This is confusing and would make better sense if it read “clinical tests for each”. Appropriate correction is requested.

Claim 21, step (c) recites “reading out each of a m clinical tests”. The claim should read either “reading out each of m clinical tests”.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 21, 23, 24, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “classifying the various subgroups”. There is insufficient antecedent basis in the claims for “the various subgroups”. No mention of any subgroup precedes the “subgroup” of step (c). Clarification is requested.

Claim 1, step (c) is also confusing, as the grammar is unclear. It is unclear what Applicant intends by the wording of this step. Perhaps the claim should read, “classifying the various subgroups of the suspected disease, said classification based on pathology, pathogenic agent, cause, and symptoms”. Clarification is requested.

Claim 1, step (d) recites “confirming the diagnosis”. There is insufficient antecedent basis for “the diagnosis” in the claim, as it was not recited previously. Clarification is requested.

Art Unit: 1631

Claim 1, step (f) recites “first of said clinical test values”. There is insufficient antecedent basis for “said clinical test values”. Where do these values originate? Clarification is requested.

Claim 1, step (g) recites “the disease-specific diagnostic algorithm”. There is insufficient antecedent basis for “the disease-specific diagnostic algorithm”. Is this intended to be the “diagnostic algorithm” from the preamble or some other algorithm? Furthermore, what disease-specific diagnostic algorithm is intended? Are the algorithms the same for every disease? Clarification is requested.

Claims 3 and 4 recite “further comprising using”. The metes and bounds of “using” are unclear. Does applicant intend that the method further comprises applying a program code or running a program code? Clarification is requested.

Claim 4 recites “using a modified computer architecture”. It is unclear what is intended by a “modified architecture”. Is this different from the code of claim 3? If so, how is it different/modified? Clarification is requested.

Claim 21, step (b) recites “diagnose a suspected test from tests ordered by a physician”. It is unclear as to what Applicant intends? Is this a means of selecting tests necessary to diagnose a suspected disease? Clarification is requested.

Claim 27, step (f) recites “the data word”. There is insufficient antecedent basis in the claims for “the data word”. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 21, 23, 24, 25, and 27 remain rejected under 35 U.S.C. 102(b) as being anticipated by Adlassnig et al. (Artificial Intelligence in Medicine (1995) Vol. 17, pages 1-24) for the reasons set forth in the Previous Office Action and re-iterated below for Applicant's convenience.

Adlassnig et al. disclose the HEPAEXPERT-1 computer algorithm that is useful in obtaining a diagnosis of HBV infection. As shown in figures 2 and 3 typical serology for a variety of types of HBV infection are used for identifying which clinical tests to run. Rules are written in to computer memory for normal and typical scenarios of HBV infection and the computer goes through a variety of test combinations to establish a diagnosis. The programmed computers of Adlassnig et al. meet all of the limitations of the instant claims.

Applicant argues that “none of the cited references have the distinguishing feature that the algorithm is run entirely by the computer and an external operator or technician cannot interfere with it. This is because the algorithm has a control system that checks against unnecessary tests right at the first stage of the invention”. While this may be the case, as was discussed and understood in the interview conducted 30 March 2004, and this may be the distinguishing feature of the instant invention, there is nothing in the claims that contains these limitations, therefore the art of Adlassnig et al. still applies.

Art Unit: 1631

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran
6/28/04

June 28, 2004
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow